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10/029,305	12/20/2001	Tyrone L. Hardy	70012-36-CIP	4390

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EXAMINER

QADERI, RUNA S

ART UNIT PAPER NUMBER

3737

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/029,305

Applicant(s)

HARDY ET AL. *CH*

Examiner

Runa S. Qaderi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

Claims 30, 31, and 39 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 30 and 31 recite the limitations to "position of sine and cosine fiducials mathematically linked" and "mathematically linked by a  $\pi/2$  relationship", respectively. It is within the common mathematical knowledge that a sine and cosine wave are mathematically linked by  $\pi/2$ . The limitations of claims 30 and 31 fail to further limit claim 29 because they reiterate an inherent feature of sine and cosine wave. A sine and cosine waveform denotes trigonometric waveforms mathematically linked by  $\pi/2$ .

Furthermore the limitation to a said trigonometric waveform fiducials having varying amplitude fails to further limit the parent claim a waveform connotes varying amplitude.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-39 fail to define the invention with a reasonable degree of clarity and precision.

Claim 32 recites, "one of said at least two fiducials is a straight line". According to claim 29 "at least two of said fiducials" are defined as being a sinusoidal and cosinusoidal waveforms. It is unclear if the "straight line" fiducial is separate from the at least two fiducials" or is one of the "at least two fiducials". If the latter is the case then the claim should read as at least three fiducials. In any event the claim is indefinite because it fails to define the invention with a reasonable degree of clarity.

Limitation of claim 33 introduces "another of said at least two fiducials is a straight line non-parallel to said first straight line fiducial". It is unclear if "another of said at least two fiducials" introduces a forth fiducial to the system or is one of the said at least two fiducials.

Claims 34 and 38 are indefinite because it is unclear if a fifth and sixth fiducials defined as "still another" and "yet another", respectively, are introduced or are they one of the "said at least two fiducials".

Claims 36 and 37 recites the limitation "non- parallel" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 38 recites the limitation "the other" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The explanations above are not complete list of the deficiencies of claims 32-39 with respect to 35 U.S.C. 112 2<sup>nd</sup> paragraph requirements. The language of claims 32-

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39 is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 28, 42, and 45 are rejected under 35 U.S.C. 102(b) as anticipated being by Wessels (US 5,299,253).

Wessels teaches an alignment system for registering a region of interest in images of modalities. The alignment of the images is provided by a support means with attached contrast markers. Wessels disclosed various patterns of the contrast markers on the support means, figures 1(a) and 1(b). The alignment system further comprises a cast that can be molded according to the patient, columns 5 and 6. The cast additionally reduces possible motion artifacts. The region of interest can be defined a body portion or the entire body. The contrast markers in addition to the body cast (partial or whole) satisfies the applicants limitation to the whole body stereotactic system. Furthermore the Wessels patent teaches that the patterns of markers on the support can comprise of at least one transversely constant marker and at least one transversely variable

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contrast marker spanning the longitudinal imaging area which satisfies limitations to the straight line fiducial pattern and trigonometric waveform fiducial pattern of Wessels.

Waveform is interpreted as an oscillating motion (the N, Z, W, etc. patterns of Wessels obviously diagrams oscillation) and trigonometric is interpreted branch of mathematics dealing with angles and triangles or trigonometric functions as sine and cosine.

Therefore according to the interpretation Wessels W, N, Z, etc. patterns clearly anticipates applicant's limitation a trigonometric waveform. In the same note a the contrast marker pattern of N, Z, etc. is inherent to be a continuous array of coupled fiducials. Wessels column 4 lines 49-53 recites that although the "alignment system is used just in one plane, there can be a series of alignment systems in planes about the object to be images". The series of planes introduces the quality assurances marker as taught by the applicant.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 27, 29-31, 40, 41, 43, 44, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wessels (US 5,299,253).

Wessels teaches an alignment system by provided a patient support with at least two marker patterns (constant and variable) attached to the patient support. Examples of fiducial patterns include but are not limited to N, Z, W, etc, which satisfy the limitation to a trigonometric waveform.

Wessels does not further define said waveform as a sine or cosine waveform. The patent does not explicitly recite alignment of the support with respect to the imaging system. Although the patent disclosed the imaging system used in accordance to a therapeutic procedure it does not explicitly recite the limitations to an arc carriage on the support and does not explicitly recite the method steps of the therapeutic procedure. Finally the specific optimization scheme is not used in the Wessels invention.

A person of ordinary skill in the art would have be motivated to provide a sine or cosine waveform pattern of the fiducials because Wessels recites that the shapes listed are not at all inclusive and any shape which would be apparent can be considered. The N, Z, and M patterns are very similar to the sine and cosine pattern and either waveform satisfies the alignment scheme. In providing a sine or cosine waveform it is inherent that the two are mathematically linked by  $\pi/2$ .

Although the patent is silent to the alignment of the support system with respect to the imaging system it would is obvious to one of ordinary skill in the art to acknowledge that the alignment system of Wessels function in spite of its alignment to the imaging system.

Furthermore Wessels column 7-9 discloses providing therapy using the alignment system. The specific method of therapy and apparatus is obvious to one of

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ordinary skill in the art at the time the invention was made because the registration of the region of interest is satisfies regardless on the specific therapeutic procedure. In addition the therapeutic procedure is contingent to the patient disorder/complication.

Finally a person of ordinary skill in the art would have been motivated to able any available optimization scheme to register the images so as long as the alignment is satisfied. Also the recitation of Wessels column 4 lines 14-17 "The operator can align the images from tow or more imaging systems by hand or by computer with specially written computer programs". This recitation does not preclude from the optimization means as defined by applicant.

### ***Response to Arguments***

Applicant's arguments with respect to claims 25-49 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Picard et al. (US 5,442,674)

Lax (US 5,681,326)

Dobbs (US 6,148,085)

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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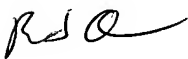
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

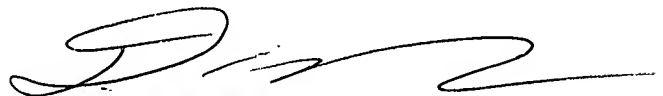
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis W. Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



RSQ



**DENNIS W. RUHL**  
**SUPERVISORY PATENT EXAMINER**